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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/527,919	03/17/00	CHATFIELD S	KC01002US

EXAMINER

HM12/0801

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ART UNIT	PAPER NUMBER
1648	17

DATE MAILED: 08/01/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary	09/527,919	CHATFIELD, STEVEN NEVILLE	
	Examiner	Art Unit	
	Bao Qun Li	1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *07 March 2001* .

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-34* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-34* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-4, 10 and 15 drawn to a fusion polypeptide and a vaccine composition comprising fusion protein comprising a tetanus toxin C fragment, pre-S1 region of HBV and pre-S2 region of HBV, classified in class 530, subclass 402.

II. Claims 5-7,16, 18-22 and 30-33, drawn to a polynucleotide sequence, a vector and a vaccine composition comprising the polynecleotide sequence of a tetanus toxin C fragment, pre-S1 region of HBV and pre-S2 region of HBV and method of using the composition, classified in class 536, subclass 23.4.

III. Claims 8-9 and 17, drawn to a host cell comprising the sequences encoding a tetanus toxin C fragment, pre-S1 region of HBV and pre-S2 region of HBV, classified in class 435, subclass 326.

IV. Claims 11 and 25-27, drawn to a method for treating HBV infection in animal with a polypeptide, classified in class 424, subclass 227.1.

V. Claims 12-13, 14 and 34, drawn to a method for raising and method of using an antibody against a polypeptide comprising the tetanus toxin C fragment, pre-S1 region of HBV and pre-S2 region of HBV, classified in class 435, subclass 326.

VI. Claims 23-24, 28-29 and 32-33, drawn to method for preventing HBV infection comprising to administering an effective amount of a polypeptide comprising a tetanus toxin C fragment, pre-S1 region of HBV and pre-S2 region of HBV, classified in class 424, subclass 196.11.

Upon election of Group I-VI, Applicant is additionally required to elect a single polypeptide or polynucleotide encoding the fusion protein comprising the fragment of a tetanus toxin C and HBV pre-S1 or pre-S2 fragment as recited in the claims 1-4 to be examined on the merits. This requirement is not to be construed as a requirement for an election of species, since each of the construct recited in alternative form is not a member of a single genus of invention, but constitutes an independent and patentably distinct invention. Each of the constructs has different molecular structure and the search of each structure would be burdensome to search in both in house and commercial databases.

The construct need to selected are as following:

a). A 6 amino acid of tetanus toxin fragment C fused with pre-S1 region of HBV polypeptide.

b). A 6 amino acid of tetanus toxin fragment C fused with pre-S2 region of HBV polypeptide.

c). A 6 amino acid of tetanus toxin fragment C fused with pre-S1 and pre-S2 region of HBV polypeptide.

e). A 6 amino acid of tetanus toxin fragment C fused with a 6 amino acids of pre-S1 regions of HBV polypeptide.

f). A 6 amino acid of tetanus toxin fragment C fused with a 6 amino acids of pre-S2 region of HBV polypeptide.

g). A 6 amino acid of tetanus toxin fragment C fused with a 6 amino acids of pre-S1 and pre-S2 region of HBV polypeptide.

f). A 100 amino acid of tetanus toxin fragment C fused with pre-S1 region of HBV polypeptide.

g). A 100 amino acid of tetanus toxin fragment C fused with pre-S2 region of HBV polypeptide.

h). A 100 amino acid of tetanus toxin fragment C fused with 6 amino acids of pre-S1 and pre-S2 region of HBV polypeptide.

i). A full length of tetanus toxin fragment C fused with pre-S1 regions of HBV polypeptide.

j). A full length of amino acid of tetanus toxin fragment C fused with pre-S2 region of HBV polypeptide.

k). A full length of tetanus toxin fragment C fused with 6 amino acids of pre-S1 and pre-S2 region of HBV polypeptide.

l). A 6 of tetanus toxin fragment C fused with a 6 amino acids of 20 amino acid of pre-S1 region of HBV polypeptide.

m). A 6 amino acid of tetanus toxin fragment C fused with 20 amino acids of pre-S2 regions of HBV polypeptide.

n). A 6 amino acid of tetanus toxin fragment C fused with 20 amino acids of pre-S1 and pre-S2 region of HBV polypeptide.

o). A 100 amino acid of tetanus toxin fragment C fused with a 20 amino acids of pre-S1 region of HBV polypeptide.

p). A 6 amino acid of tetanus toxin fragment C fused with a 20 amino acids of pre-S2 region of HBV polypeptide.

q). A 100 amino acid of tetanus toxin fragment C fused with 20 amino acids of pre-S1 and pre-S2 region of HBV polypeptide.

r). A full length of tetanus toxin fragment C fused with 20 amino acids of pre-S1 region of HBV polypeptide.

s). A full length of tetanus toxin fragment C fused with 20 amino acids of pre-S2 region of HBV polypeptide.

t). A full length of tetanus toxin fragment C fused with a 20amino acids of pre-S1 and pre-S2 region of HBV polypeptide.

Inventions of groups I-III are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions of Groups I-III are directed to structurally different product, e.g. the product of the Group I is a polypeptide, whereas the product of the group III is a cells.

Inventions of groups IV to VI are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions of Groups IV to VI are directed to different method for different purposes, e.g. the method of the Group IV is a treatment of HBV with polypeptide, whereas the method of the group V is method for raising antibody.

Inventions I and IV are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the product as claimed can be used in a material different process, such as to raise an antibody.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bao Qun Li whose telephone number is 703-305-1695. The examiner can normally be reached on 8:00 to 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel can be reached on 703-308-4027. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4242 for regular communications and 703-308-4242 for After Final communications.
Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Bao Qun Li

July 25, 2001

James C. Housel 7/30/01
JAMES HOUSEL
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600